## REMARKS/ARGUMENTS

This is in response to a communication received from the Examiner in charge of the subject application, which communication was mailed on August 1, 2005.

In the communication mailed August 1st the Examiner has rejected claims 50 through 54. In view of the following remarks, reconsideration of such rejection is respectfully requested.

Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClelland et al. (US 5,350,584) in view of Chow et al. (US 4,859,461) and further in view of Bodmeier et al. ("Effect of ion exchange resins on the drug release from matrix tablets," in European Journal of Pharmaceutics and Biopharmaceutics, 46, (1998), pp 321-327; provided by applicants).

McClelland et al. teaches a novel process for the spheronization of charged resins. Spherical multiparticulates are produced, and such spheres range in size from 0.3 mm to 3 mm in diameter. The spherical particle product is microcrystalline-free. The process as taught by McClelland at al. comprises the steps of mixing, followed by wet granulation, spheronization and finally drying.

McClelland's invention and formulations pertain to processes and ingredients used to make spheronized particles, specifically the use of charged resins in place of microcrystalline cellulose. The process requires wet granulation, extruding and spheronizing. Additionally, McClelland indicates that the medicament may be incorporated into the backbone of a polymer or may be incorporated into the backbone of the charged resin used in the formulation.

The present invention does not require any of these manufacturing steps (wet granulation, spheronization and drying). The drug in the present invention is not incorporated into the backbone of a polymer nor is it incorporated into the backbone of the charged resin used in the formulation. The teaching of McClelland does not render obvious the invention as claimed.

The Chow et al. patent describes a process by which sulfonic acid cation exchange resin particles are treated with an impregnating agent to improve the particles' coatability. Basic drugs are adsorbed onto the treated resin particles, thereby forming a drug-resin complex. The particles may then be coated by up to about 3 to 20% by weight of a diffusion barrier membrane material. The coated and uncoated particles may then be blended in various proportions to give desired dissolution profiles.

The present invention does not require or include coating of the ion exchange resin prior to incorporation into a dosage form, nor does it describe the adsorption of drug onto the ion exchange resin to form drug-resin particles.

Combining the teachings cited by the Examiner, to prepare an oxycodone composition of McClelland and use hydroxypropylmethylcellulose (HPMC) as the carrier, the individual skilled in the art would have preloaded the oxycodone onto the resin backbone, then wet granulated the loaded resin with HPMC, extruding, spheronizing and drying the spheres, all prior to manufacturing the dosage form. One of ordinary skill in the art would not know through the combined teachings of McClelland and Chow et al. that a combination of ingredients without any pre-treatment, drug loading, wet granulating, spheronization and coating would result in a surprisingly slow release medicament. In addition, McClelland and Chow do not include the use of phenolic amine resin.

Although the compositions of McClelland and Chow may be somewhat similar, how the ingredients are combined into a dosage form is vastly different. The manufacturing processes and teachings are completely different, and thus it would not be obvious to one of ordinary skill in the art to prepare the compositions described in the present invention by following the teachings of McClelland and Chow.

The subject application describes a solid oral dosage form containing an opioid drug, polymer and ion exchange resin manufactured by dry admixture of the ingredients without any pretreatments or post treatments (coating). Upon contact with the dissolution medium,

a gel layer is formed around the tablet. Within this gel layer a complex is formed between the drug and ion exchange resin. The drug, when replaced by counter ions in the dissolution medium, is released by diffusion through the gel layer. This "in situ" method of drug-complex formation is advantageous in that it simplifies the manufacturing process as compared to the processes described in 5,980,882, 4,160,827, 5,413,782, 4,221,778, 5,368,852 and many other US and foreign patents where a drug-resin complex is formed prior to incorporation into a pharmaceutically active dosage form.

Concerning the additional rejection of claims 50 and 54 over McClelland, Chow and Eichman, U.S. Pat. 5,980,882, Eichman discloses the stabilization of a drug resin complex by use of a chelating agent, preferably EDTA. Eichman describes a method of making a pharmaceutical composition comprising: (a) combining a drug and an ion exchange resin in a liquid to form a drug resin complex; (b) adding a chelating agent; and (c) drying the result from step (b) to form a solid or gel pharmaceutical composition. (column 3, lines 30-36). Eichman describes formation of dosage forms containing drug/resin complexes which also have increased chemical stability by use of chelating agents used during the formation of the drug-resin complex. Eichman also describes coating of the drug-resin complex particles.

Although Eichman does describe the use of phenolic amine resin IRP- 69 and IRP-70, the use of such resins in only described in the context of producing a drug resin complex, and the stabilization of the complex by the addition of a chelating agent to the complex. As set forth above this is very different from the invention of the subject application.

In view of the foregoing, it is respectfully submitted that the subject application is in condition for allowance and such favorable action at an early date is earnestly solicited.

Respectfully submitted,

Mary-Ellen M. Devlin
Attorney for Applicant(s)
Reg. No. 27,928

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 798-4866
Dated: November 15, 2005

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on November 15, 2005

By: Mary-Ellen M. Devlin
Reg. No. 27,928